Amendments to the Specification:

Please replace the Title on p. 1, lines 1 and 2 with the following amended Title:

METHOD OF INSERTING DOUBLE-Y-SHAPED CATHETER WITH ATTACHABLE HUBS

Please replace the paragraph on page 1, beginning at line 5, with the following amended paragraph:

This application is a continuation of pending U.S. Patent Application Serial No. 10/231,748, which is a continuation-in-part of U.S. Patent Application Serial No. 10/086,033, filed February 28, 2002, now Pat. No. 6,638,242, which is a continuation of ~~pending~~ U.S. Patent Application Serial No. 09/769,052, filed January 24, 2001, abandoned.

Please replace the paragraph beginning on page 1, at line 23, with the following amended paragraph:

While double lumen catheters (e.g., U.S. Pat. No. 4,895,561) allow for a single insertion of the catheter into the desired vein, double lumen catheters typically do not permit optimal catheter tip placement. Due to differences among patients, optimal tip position varies from patient to patient. Non-optimal tip position may significantly lower flow values, resulting in less effective dialysis treatment. For current double lumen catheters, a physician must make an estimate regarding the appropriate catheter tube length prior to beginning the procedure of catheterization. Then, a subcutaneous tunnel is made from a first end, which is near the area to be

catheterized, to a second end, which is the preferred end position of the hub assembly, namely, away from the neck of the patient, in order to allow for more convenient access to the dialysis treatment equipment. The catheter tube is then routed forwardly ~~into the~~ through the subcutaneous tunnel from the second end to the first end so that the catheter tips extend outwardly from the first end of the tunnel. Either before or after tunneling, a sheath is inserted ~~trough~~ through the first end of the tunnel and into the area to be catheterized, and the catheter tips are inserted into the sheath and the area to be catheterized. The estimated catheter tube length and subsequent forward tunneling may result in less than optimal tip placement.

Please replace the paragraph beginning on page 2, at line 14, with the following amended paragraph:

With the use of two independent single lumen catheters (e.g., U.S. Pat. No. 5,776,111 to Tesio) the problem of tip placement is addressed. The hub assembly of each catheter is removable from the tube and tip portion of the catheter, thereby allowing the catheter tip to be placed directly into the vein and advanced into the desired position. Then, the proximal end of the catheter can be ~~reversed~~ reverse tunneled and trimmed to a desired length. Thereafter, the hub assembly is attached. Deficiencies, however, exist in this method of catheterization as well. One problem associated with this method is that this method requires two separate venous insertions, namely, two tunnels and two of each accessory instrument used for the procedure. Therefore, there is increased surgical time required to place two catheters, there are two wound entry sites which doubles the risk of post-surgical

infection, and the two catheters together are significantly larger in diameter than one double lumen catheter.

Please replace the paragraph on page 4, beginning at line 5, with the following amended paragraph:

Therefore, there is a need for multi-lumen catheter that can be inserted into a patient using a reverse tunneling technique, which permits accurate placement of the tips of the catheter into the area to be catheterized and that is selectively attachable to a fluid exchange device. The improved catheter should not ~~required~~ require an extensive hub assembly, thus making it relatively inexpensive to manufacture and easy to insert into a patient.

Please replace the paragraph beginning on page 4, at line 12, with the following amended paragraph:

A multi-lumen catheter is provided for use in hemodialysis and the like. The multi-lumen catheter includes an elongated, central, multi-lumen tube portion having a distal end and a proximal end. The central tube portion has a substantially cylindrical outer shape and is internally segmented into a plurality of lumens. A distal branch portion includes a plurality of single-lumen distal extension tubes. Each distal extension tube has a proximal first end and a distal second end. The proximal first end of each distal extension tube is connected to the distal end of the central tube portion such that the single lumen of each distal extension tube is in fluid communication with one of the plurality of lumens of the central tube portion. A proximal branch portion includes a plurality of single-lumen proximal extension

tubes. Each proximal extension tube has a distal first end and a proximal second end. The distal first end of each proximal extension tube is connected to the proximal end of the central tube portion such that the single lumen of each distal extension tube is in fluid communication with one of the plurality of lumens of the central tube portion. A plurality of selectively attachable connector hubs are provided, each connector hub being configured to be selectively attachable to the distal second end of one of the distal ~~extension~~ extensions and being configured for selective connection to a fluid exchange device. Each lumen of the central tube portion and the lumens of the distal and proximal extension tubes in fluid communication therewith define a flow path through the catheter. An in-growth stabilizing cuff may be affixed to an outer portion of the central tube portion.

Please replace the paragraph beginning on page 5, at line 16, with the following amended paragraph:

The central tube portion, the distal extension tubes, and the proximal extension tubes may be comprised of a fusible material, and the distal extension tubes and proximal extension tubes may be respectively fused to the distal and proximal ends of the central tube portion. The distal extension tubes may have a substantially cylindrical outer shape near their distal second ends, and the proximal multi-lumen connection portion may also have a substantially cylindrical outer shape. The proximal extension tubes may have a substantially D-shaped cross-section over at least a portion of their length. Also, the proximal extension tubes may be substantially parallel to each other in a free state, and the proximal second ends of the distal extension tubes may be longitudinally spaced from each other.

Please replace the paragraph on page 6, beginning at line 3, with the following amended paragraph:

The multi-lumen catheter may further include a plurality of connector hubs for connecting the catheter to a fluid exchange device. Each connector hub may be configured to be connected to the distal second end of one of the distal extension tubes, and configured for connection to a portion of a fluid exchange ~~apparatus~~ device. Each of the proximal extension tubes may include a tube wall, and each of the proximal extension tubes may include at least one opening extending through its tube wall. Further, an external portion of at least one of the distal extension tubes may include indicia which indicates a discrete flow path through the catheter.[[.]] In one arrangement, the two proximal extension tubes have longitudinal axes which intersect at an included angle in a free state, the included angle being in a range from about 10 degrees to about 30 degrees.

Please replace the paragraph on page 7, beginning at line 11, with the following amended paragraph:

The method of forming a multi-lumen catheter may include first forming a y-shaped distal junction. The process may include providing a first length of single-lumen tubing to form a distal arterial extension tube, providing a second length of single-lumen tubing to form a distal ~~venal~~ veinal extension tube, providing a first length of multi-lumen tubing comprising at least an arterial lumen and a ~~venal~~ veinal lumen, and having a distal end and a proximal end, attaching an end of the distal arterial extension tube to the distal end of the first length of multi-lumen

tubing such that the distal arterial extension tube is in fluid communication with the arterial lumen of the first length of multi-lumen tubing, and attaching an end of the distal ~~venal~~ veinal extension tube to the distal end of the first length of multi-lumen tubing such that the distal ~~venal~~ veinal extension tube is in fluid communication with the ~~venal~~ veinal lumen of the first length of multi-lumen tubing. The proximal end of the first length of multi-lumen tubing forms a connecting end.

Please replace the paragraph beginning on page 7, at line 22, with the following amended paragraph:

A second length of multi-lumen tubing having a distal end and a proximal end is provided. The tubing includes an arterial lumen and a ~~venal~~ veinal lumen. The connecting end of the first length of multi-lumen tubing is connected to the distal end of the second length of multi-lumen tubing, such that the arterial extension tube of the distal junction is in fluid communication with the arterial lumen of the second length of multi-lumen tubing, and the ~~venal~~ veinal extension tube of the distal junction is in fluid communication with the ~~venal~~ veinal lumen of the second length of multi-lumen tubing.

Please replace the paragraph on page 8, beginning at line 6, with the following amended paragraph:

A y-shaped proximal junction is also formed. This process includes providing a third length of single-lumen tubing to form a proximal arterial extension tube, and providing a fourth length of single-lumen tubing to form a proximal ~~venal~~ veinal extension tube. A third length of multi-lumen tubing is also provided which includes

at least an arterial lumen and a ~~venal~~ veinal lumen, and has a distal end and a proximal end. An end of the proximal arterial extension tube is attached to the distal end of the third length of multi-lumen tubing such that the proximal arterial extension tube is in fluid communication with the arterial lumen of the third length of multi-lumen tubing, Also, an end of the proximal ~~venal~~ veinal extension tube is attached to the distal end of the third length of multi-lumen tubing such that the proximal ~~venal~~ veinal extension tube is in fluid communication with the ~~venal~~ veinal lumen of the third length of multi-lumen tubing. The distal end of the third length of multi-lumen tubing forms an attachment end.

Please replace the paragraph beginning on page 8, at line 17, with the following amended paragraph:

The attachment end of the third length of multi-lumen tubing is attached to the proximal end of the second length of multi-lumen tubing, such that the arterial extension tube of the proximal junction is in fluid communication with the arterial lumen of the second length of multi-lumen tubing, and the ~~venal~~ veinal extension tube of the proximal junction is in fluid communication with the ~~venal~~ veinal lumen of the second length of multi-lumen tubing. The method may also include forming at least one opening in a wall of the proximal ~~venal~~ veinal extension tube, and forming at least one opening in a wall of the arterial proximal extension tube. The steps of attaching extension tubes and lengths of multi-lumen tubing together or to each other may include heat welding or similar fusing techniques. The longitudinal axes of the distal arterial extension tube and distal ~~venal~~ veinal extension may be arranged to intersect at an included angle in a free state in a range from about 10 degrees to about 30 degrees.

Please replace the paragraph on page 9, beginning at line 5, with the following amended paragraph:

A method for surgically implanting a ~~double-y shaped~~ double-Y-shaped multi-lumen catheter into a patient is also provided. The method is suited for implanting a multi-lumen catheter having [[a]] an elongated, central, multi-lumen tube portion, a proximal end portion including a single-lumen proximal ~~venal~~ veinal extension tube and a single-lumen proximal arterial extension tube each having a proximal tip, and a distal end portion including a single-lumen distal ~~venal~~ veinal extension tube and a single-lumen distal arterial extension tube each having a distal end. The method includes making an incision in the skin of the patient, and inserting the proximal tips of the proximal ~~venal~~ veinal and arterial extension tubes through the incision and placing the proximal tips in the patient. A subcutaneous tunnel is formed having a first end proximate to the incision and second end remote from the first end of the tunnel. The distal ~~venal~~ veinal and arterial extension tubes and at least a portion of the central tube portion are guided through the subcutaneous tunnel such that at least the distal ends of the distal ~~venal~~ veinal and arterial extension tubes extend outwardly from the tunnel through the second end of the tunnel. At least a portion of the distal end portion of the catheter is secured to the patient such as by sutures or any other suitable means.[[.]]

Please replace the paragraph on page 10, beginning at line 1, with the following amended paragraph:

The catheter implanting method may further include respectively connecting the distal arterial and ~~venal~~ veinal extension tubes to arterial and ~~venal~~ veinal legs of a fluid exchange device. Connecting the distal arterial and ~~venal~~ veinal extension tubes may include connecting the distal arterial extension tube to the arterial leg with a first connector hub, and connecting the proximal ~~venal~~ veinal extension tubes to the ~~venal~~ veinal leg with a second connector hub. Inserting the proximal tips of the proximal ~~venal~~ veinal and arterial extension tubes into a patient may include placing the proximal tip of the ~~venal~~ veinal extension tube into a vein in the patient, and placing the proximal tip of the arterial extension tube into an artery in the patient.

Please replace the paragraph beginning on page 11, at line 13, with the following amended paragraph:

Figure 1 shows a ~~double-Y-shaped~~ double-Y-shaped multi-lumen catheter 10 according to the present invention. The catheter 10 includes a proximal end 34 for insertion into a patient, and a distal end 36 for connection to a fluid exchange device, such as a dialysis machine or the like. The catheter 10 includes an elongated, central, multi-lumen tube portion 12, a plurality of proximal single-lumen extension tubes 14, 16, and a plurality of distal single-lumen extension tubes 18, 20. In the embodiment shown, the central tube portion 12 includes an arterial lumen 5 and a ~~venal~~ veinal lumen 6. In this arrangement, the catheter 10 includes a proximal ~~venal~~ veinal extension tube 14 and a distal ~~venal~~ veinal extension tube 18 in fluid communication with the ~~venal~~ veinal lumen 6, and a proximal arterial extension tube 16 and a distal arterial extension tube in fluid communication with the arterial lumen 5. The catheter 10 may include a stabilizing cuff 15 affixed to an outer

portion of the central tube portion 12 as shown in Figure 1. Preferably, the cuff 15 is longitudinally positioned on the central tube portion 12 such that the cuff 15 will be finally positioned in a subcutaneous tunnel in a patient as described more fully below.

Please replace the paragraph on page 12, beginning at line 3, with the following amended paragraph:

A construction for the distal end 36 of the multi-lumen catheter 10 is shown in Figures 1-3. As shown in Figures 2 and 3, the proximal ends 18p, 20p of the distal extension tubes 18, 20 may be connected to a distal end 12d of the central tube portion 12 by a distal multi-lumen trunk 30. The multiple lumens of the distal trunk 30 correspond in number to the multiple lumens of the central tube portion 12 and the number of distal extension tubes 18, 20. In the illustrated embodiment, the distal trunk 30 includes a ~~venal~~ veinal distal trunk lumen 48, and an arterial distal trunk lumen 47 as shown in Figure 2. As shown in Figure 3, the proximal ends 18p, 20p of the distal extension tubes 18, 20 are connected to the distal end 30d of the distal trunk, thereby forming a substantially Y-shaped junction. The proximal end 30p of the distal trunk 30 is connected to the distal end 12d of the central tube portion 12 as shown in Figure 2, thereby forming a Y-shaped distal end 36. Preferably, the proximal end 30p of the distal trunk 30 is substantially cylindrical in shape, and is substantially equal in outer diameter to the outer diameter of the central tube portion 12, thereby providing a smooth transition at the juncture between the distal trunk 30 and the central tube portion 12.

Please replace the paragraph beginning on page 12, at line 17, with the following amended paragraph:

As shown in Figure 2, the distal extension tubes are arranged such that an included angle "?" exists between the longitudinal axes of the tubes 18, 20 in a free state. In a preferred arrangement, the angle "?" ranges from about 10 degrees to about 30 degrees. The distal extension tubes 18, 20 can be arranged, however, so that the angle "?" is any desired angle. The ~~venal~~ veinal distal trunk lumen 48 is in fluid communication with the ~~venal~~ veinal lumen 6 of the central tube portion 12 and the single lumen of t he distal ~~venal~~ extension tube 18. Similarly, the arterial distal trunk lumen 47 is in fluid communication with the arterial lumen 5 of the central tube portion 12 and the single lumen of the distal arterial extension tube 20.

Please replace the paragraph on page 13, beginning at line 10, with the following amended paragraph:

As shown in Figures 1-3, the catheter 10 also includes selectively attachable connector hubs 72, 74 on the distal ends 18d, 20d of the distal extension tubes 18, 20. As will be described in detail below, the connector hubs 72, 74 are selectively attachable so that the connector hubs 72, 74 can be attached to and removed from the distal end 36 of the catheter 10 after insertion of the proximal end 34 of the catheter 10 into a patient, and afer reverse, subcutaneous tunneling of the distal end 36 As shown in Figures 1 and 2, the connector hubs 72, 74 are configured for selectively sealable attachment between the distal ends 18d, 20d of the distal extension tubes 18, 20 and legs of a fluid exchange device. The connector hubs. The ~~venal~~ veinal connector hub [[74]] 72 is selectively attached to the distal portion 18d

of the distal ~~venal~~ veinal extension tube 18, and the arterial connector hub [[72]] 74 is selectively attachable to the distal portion 20d, of the distal arterial extension tube 20.

Please replace the paragraph beginning on page 13, at line 21, with the following amended paragraph:

In one embodiment as shown in Figures 1-3, the selectively attachable hubs 72, 74 are connectable with mating compression fittings 58, 60. The compression fittings may include cannulae 66, 68 and threaded male portions 62, 64 that matingly engage the distal extension tubes 18, 20 and the connector hubs 72, 74 as shown in Figure 2. When fully engaged, the hubs 72, 74 and compression fittings 58, 60 compress compression sleeves 70 about the distal portions 18d, 20d of the distal extension tubes 18, 20, thereby forming sealed connections. The compression fittings 58, 60 may be further connected to luer-type fittings 50, 52 or the like by connector tubes 54, 56. The luer-type fittings 50, 52 may then be connected to corresponding luer-type connection mechanisms on a fluid exchange device 200. For example, the distal ends of the luer-type fittings 50, 52 may include quarter-turn type threads for leak-tight engagement with matching quarter-turn fittings on the ~~venal~~ veinal and arterial legs of a fluid exchange device 200. Other types of know leak-tight selectively attachable connection configurations may also be used.

Please replace the paragraph beginning on page 14, at line 20, with the following amended paragraph:

A construction for the proximal end 34 of the catheter 10 is shown in Figures 1, 4, and 5. The distal ends 14d, 16d of the proximal extension tubes 14, 16 may be connected to a proximal end 12p of the central tube portion 12 by a proximal multi-lumen trunk 32. The lumens of the proximal trunk 32 correspond in number to the multiple lumens of the central tube portion 12 and to the number of proximal extension tubes 14, 16. In the illustrated embodiment, the proximal trunk 32 includes a ~~venal~~ veinal proximal trunk lumen 31, and an arterial proximal trunk lumen 33 as shown in Figure 5. As shown in Figure 4, the distal ends 14d, 16d of the proximal extension tubes 14, 16 are connected to the proximal end 32p of the proximal trunk 32, thereby forming a substantially Y-shaped junction. The distal end 32d of the proximal trunk 32 is connected to the proximal end 12p of the central tube portion 12 as shown in Figure 5, thereby forming a substantially Y-shaped proximal end 34 on the catheter 10. Preferably, the distal end 32d of the proximal trunk 32 is substantially cylindrical in shape, and is substantially equal in outer diameter to the outer diameter of the central tube portion 12, thereby providing a smooth transition at the juncture between the proximal trunk 32 and the central tube portion 12.

Please replace the paragraph on page 15, beginning at line 11, with the following amended paragraph:

As shown in Figure [[4]] 5, the proximal extension tubes are arranged such that an included angle "a" exists between the longitudinal axes of the tubes 14, 16 in a free state. In a preferred arrangement, the angle "a" is about 5 degrees in a rest position or free state. The ~~distal~~ proximal extension tubes [[18, 20]] 14, 16 can be arranged, however, so that the angle "a" is any desired angle. The ~~venal~~ veinal

proximal trunk lumen 31 is in fluid communication with the ~~venal~~ veinal lumen 6 of the central tube portion 12 and the single lumen of the proximal ~~venal~~ veinal extension tube 14. Similarly, the arterial proximal trunk lumen 33 is in fluid communication with the arterial lumen 5 of the central tube portion 12 and the single lumen of the proximal arterial extension tube 16.

Please replace the paragraph on page 16, beginning at line 3, with the following amended paragraph:

As shown in Figures 1, 4, and 5, the proximal arterial extension tube 16 is preferably shorter in length than the proximal ~~venal~~ veinal extension tube 14. For example, the proximal arterial extension tube 16 may be about 4 cm shorter in length than the proximal ~~venal~~ veinal extension tube 14. The resulting longitudinal spacing between the proximal tips 14p and 16p facilitates optimal proximal tip placement in a patient. As shown in Figure 4, the proximal ~~venal~~ veinal extension tube 14 may include an end opening 43 in or near its proximal tip 14p. The proximal ~~venal~~ veinal extension tube 14 may also include one or more transverse openings 42 in its tube wall 40. Similarly, as also shown in Figure 4, the proximal arterial extension tube 16 may include an end opening 47 in or near its proximal tip 16p. The proximal arterial extension tube 16 may also include one or more transverse openings 46 in its tube wall 44. The openings 42, 43, 46, and 47 facilitate fluid flow into or out from the proximal extension tubes 14, 16.

Please replace the paragraph on page 18, beginning at line 10, with the following amended paragraph:

As shown in Figure 6C, the distal end 36 of the catheter 10 is drawn from the second end [[104]] 106 of the tunnel 102 such that the distal extension tubes 18, 20 and at least a portion of the central tube portion 12 extends from the second end [[104]] 106 and the catheter 10 is fully tunneled in the patient. The incision 100 and the second end [[104]] 106 of the tunnel are suitably treated and dressed.

Please replace the paragraph on page 19, beginning at line 7, with the following amended paragraph:

As shown in Figure 6D, the catheter 10 is connected to a fluid exchange device 200. The distal end 18d of the distal ~~venal~~ veinal extension tube 18 is selectively attached to a ~~venal~~ veinal leg 228 of the fluid exchange device 200 by connector hub [[74]] 72. Similarly, the distal end 20d of the distal arterial extension tube 20 is selectively attached to an arterial leg 222 of the fluid exchange device 200 by connector hub [[72]] 74. As shown in Figure 3, indicia 26 and 28 may be included on the distal extension tubes 18, 20 and/or the connector hubs 72, 74 to assist medical personnel in identifying the proper distal extension tube 18 or 20 for connection to a corresponding leg of the fluid exchange device [[300]] 200. The indicia 26, 28 may be markings, colors, or any other distinctive indicator.